IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

IN RE: GENENTECH, INC.,	)	
HERCEPTIN (TRASTUZUMAB)	)	MDL DOCKET NO. 16-MD-2700
MARKETING AND SALES	)	ALL CASES
PRACTICES LITIGATION	)	

GENENTECH, INC.'S MOTION FOR PROTECTIVE ORDER
AND BRIEF IN SUPPORT

Defendant Genentech, Inc. ("Genentech"), pursuant to Federal Rule of Civil Procedure 26(c), respectfully requests that the Court enter a protective order limiting the disclosure of certain documents produced by Genentech and designated as "Attorneys' Eyes Only" to Plaintiffs' counsel and retained expert(s). This protection is critical to safeguard Genentech's extremely sensitive confidential commercial, proprietary and trade secret information.

INTRODUCTION

Since the commencement of this litigation, Genentech has asserted the importance of protecting its highly sensitive trade secret information from unnecessary and harmful disclosure. Plaintiffs, conversely, have consistently minimized and deflected Genentech's concerns, asserting at various times that Plaintiffs may not ultimately seek sensitive documents in discovery[1] and that, even if they did, there is no

[1] *See* Transcript of January 7, 2016 Hearing, at 24:18-20 (attached as Exhibit 1).

"real issue" with disclosing Genentech's trade secret information to dozens of individuals.[2]

Plaintiffs' assurances have proven hollow. Discovery has commenced on the limited issue of whether Plaintiffs' claims are preempted by federal law. In response to Plaintiffs' requests for production of documents following the Case Management Conference, Genentech produced the Chemistry, Manufacturing, and Controls section of its initial Biologics License Application for Herceptin® (the "CMC" of the "Herceptin® BLA").[3] The CMC section contains the information considered by the Food and Drug Administration ("FDA") in approving the specifications for drug product protein content for Herceptin 440 mg for distribution in the United States. It also includes responses to review questions posed by the FDA regarding the CMC section, as well as Genentech's commitments from a pre-license inspection.

As set forth in Genentech's prior briefs, statements to the Court, and in detail below, the Herceptin® BLA is rife with highly sensitive and commercially valuable trade secrets. In contrast to the value of these documents to Genentech, most of the information contained in the Herceptin® BLA has no relevance to Plaintiffs' claims, particularly the limited issue of federal preemption.

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[2] *See* Transcript of Case Management Conference (June 23, 2016), at 38:8-14 (attached as Exhibit 2).

[3] *See* Genentech, Inc.'s Responses and Objections to the Portions of Plaintiff's First Set of Discovery Requests Adopted by Plaintiffs Following CMO No. 1, Response to RFP Nos. 4, 5, 6, and 7 (attached as Exhibit 3).

In light of these concerns, Genentech's production designated the CMC of the Herceptin® BLA as "Highly Confidential—Attorneys' Eyes Only" and noted in its cover letter to Plaintiffs that certain documents were so designated. *See* Letter from W. O'Connor to D. Keglovits dated July 12, 2016 (attached as Exhibit 4). On July 15, counsel for Plaintiffs informed Genentech by letter that it did not intend to honor Genentech's Attorneys' Eyes Only designation. That letter necessitated this Motion.[4]

At the Case Management Conference, the Court recognized Genentech's concerns regarding **this exact set of documents**—the Herceptin® BLA. Counsel for Genentech reiterated the risks posed by unlimited disclosure of its trade secrets. Plaintiffs, in turn, offered no coherent justification for revealing extremely sensitive documents to dozens of Plaintiffs' designated representatives, who have no relevant expertise that would benefit Plaintiffs. In light of Genentech's concerns, the Court permitted Genentech to seek Attorneys' Eyes Only protection on a "case-by-case basis." *See* Exhibit 2, at 41:16-21. The Court incorporated this ruling into the Case Management Order, stating: "the Court will entertain Defendants' request for 'attorney's eyes only' protection on specific documents related to trade secrets and pricing information on a case-by-case basis as the need arises." [Dkt. No. 39], Section 4(c).

Pursuant to the Court's direction at the Case Management Conference, the Case Management Order, and Federal Rule of Civil Procedure 26(c)(1)(G), Genentech

[4] Counsel for Genentech and Plaintiffs have met and conferred in good faith regarding this matter but have been unable to reach a resolution. *See* Fed. R. Civ. P. 26(c).

respectfully requests that the Court enter a Protective Order limiting the disclosure of documents designated as Attorneys' Eyes Only to Plaintiffs' counsel and retained expert(s).

ARGUMENT AND AUTHORITIES

I. The Federal Rules of Civil Procedure Authorize Enhanced Protections for Trade Secrets, and Courts Regularly Order Attorneys' Eyes Only Protection.

Federal Rule of Civil Procedure 26(c)(1)(G) expressly contemplates protective orders "requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way." Indeed, the Tenth Circuit Court of Appeals has expressly acknowledged "[t]he disclosure of confidential information on an 'attorneys' eyes only' basis is a routine feature of civil litigation involving trade secrets." *Paycom Payroll, LLC v. Richison*, 758 F.3d 1198, 1202-03 (10th Cir. 2014) (emphasis added) (quoting *In re City of New York*, 607 F.3d 923, 935 (2d Cir. 2010) and citing FED. R. CIV. P. 26(c)(1)(G). The court in *Richison* explained "[t]he purpose of this form of limited disclosure is to **prevent a party** from viewing the sensitive information while nevertheless **allowing the party's lawyers** to litigate on the basis of that information." *Id.* (emphases added). This protection is so vital that "a court may impose such a restriction over the objection of a party." *Id*.

In accordance with that well-established principle, this Court has routinely entered protective orders containing Attorneys' Eyes Only provisions. *See, e.g.*, *Littlebear v. Advanced Bionics, LLC*, No. 11-CV-418-GKF-PJC, 2012 U.S. Dist. LEXIS 100791, at *5

(N.D. Okla. July 20, 2012); *CTI Servs. LLC v. Haremza*, No. 09-CV-144-GKF-TLW, 2011 U.S. Dist. LEXIS 53478, at *2 (N.D. Okla. May 17, 2011); *Legates v. State ex rel. Rogers Cty. Dep't of Human Servs.*, No. 09-CV-29-TCK-FHM, 2009 U.S. Dist. LEXIS 85511 (N.D. Okla. Sep. 18, 2009). The Court explained in *Littlebear* "that an 'Attorneys' Eyes Only" provision is appropriate [because]. . . . [t]he danger of proprietary and highly confidential information being disclosed to and used by a competitor of Defendant entitles such information to heightened protection." 2012 U.S. Dist. LEXIS 100791, at *5.

II. Attorneys' Eyes Only Protection is Essential to Protect Genentech's Highly Sensitive and Commercially Valuable Trade Secrets.

Genentech seeks Attorneys' Eyes Only protection for the CMC of the Herceptin® BLA, which it produced to Plaintiffs on July 12, 2016. *See* Exhibit 3, Response to RFP Nos. 4, 5, 6, and 7. A BLA is submitted to the FDA seeking permission to introduce, or deliver for introduction, a biologic product into interstate commerce. *See* 21 C.F.R. § 601.2; *see also* Frydenlund Decl. at ¶ 5 (attached as Exhibit 5). Much of the information contained within the Herceptin® BLA is highly confidential, commercially sensitive, trade secret information not generally known to the public. Genentech has always shielded this information from disclosure. *See id.* at ¶¶ 5-10. In particular, "portions of the Herceptin BLA are also highly confidential because information derived from them regarding the formulation, manufacturing, and testing of drugs, if disclosed, would provide competitors with insights into Genentech's strategy for developing new drugs."

Id. ¶ 7. The potential loss to Genentech is "a decade of research and development, millions of dollars, and considerable human capital." *Id.* ¶ 9.

In light of its commercial sensitivity, portions of the BLA have previously been produced under an Attorneys' Eyes Only provision such as the one Genentech seeks here. *See* Attorneys' Eyes Only provisions in the two Stipulated Protective Orders in *Genentech, Inc. v. Trustees of Univ. of. Penn.*, Case No: 5:10-CV-2037-LHK-PVT (N.D. Cal.) (attached as Exhibit Nos. 6 and 7).

At the Case Management Conference, Counsel for Genentech articulated Genentech's specific confidentiality concerns with respect to the Herceptin® BLA:

> MS. DONAHUE: There's one provision of the Protective Order that [the Court] entered that we at Genentech have issue with. . . . and it's very important to Genentech in terms of their highly confidential information that much of this discovery; in fact, all of this discovery will be put on the table. **You know, most of our manufacturing documents are formulas, are very highly confidential**. . . .
>
> Now, we're concerned . . . solely about the regulatory information for this phase. And I wanted to add that if the plaintiffs were to go to the FDA and request, **for instance, our biologic licensing application**, it would come back to them highly redacted because of the trade secret information that's contained therein.

See Exhibit 2 at 35:18-25; 36:1-5; 40:6-15 (emphases added). In response to these concerns, the Court stated:

> THE COURT: All right. I'm going to sustain Magistrate Wilson's position and order on the Protective Order with the exception that, you know, **we'll entertain on a case-by-case basis the specific matters that relate to trade secrets and pricing**.

Id. at 41:16-21 (emphasis added).

Genentech plainly has established that its trade secrets contained in the Herceptin® BLA are highly sensitive and commercially valuable. Plaintiffs, by contrast have **never** articulated how they may benefit from disclosing this information to their designated representatives, who, according to Plaintiffs, are "practicing oncologists." *Id.* at 37:22-25; 38:1-7. Counsel for Plaintiffs baldly asserted that Plaintiffs "benefit greatly from their help in understanding the information we get." *Id.* Yet, with respect to the Herceptin® BLA *in particular*, Plaintiffs have never explained how they could benefit from disclosing this information to a practicing oncologist with no expertise (or even experience) with the FDA approval process or with the formulation, manufacture, or testing of prescription drugs.

Because Genentech has shown why its trade secrets deserve the protection of Rule 26(c)(1)(G), the burden lies with Plaintiffs to explain how their designated representatives, who have no relevant expertise, could benefit from viewing this information. Indeed, the burden on Plaintiffs is even greater because most of the information contained in the Herceptin® BLA is *wholly irrelevant* to Plaintiffs' claims, particularly in the limited context of federal preemption.

At the Case Management Conference, the Court ruled that the initial phase of discovery in this action is limited to "issues that bear on or reasonably might bear on the question of the Federal preemption." Exhibit 2, at 32:15-18. Genentech's

preemption defense is based on two independent grounds. First, Plaintiffs' state-law claims conflict with federal law because they would require Genentech to ensure that each vial of Herceptin is filled with exactly or no less than 440 mg, which directly conflicts with Congress's express determination to permit reasonable variations in the net contents of prescription drugs, as implemented through FDA regulations. *See* 21 U.S.C. § 352(b); 21 C.F.R. § 201.51(g).

Second, Plaintiffs' claims are preempted because ensuring that each vial of Herceptin contains exactly or no less than 440 mg would require Genentech to change its manufacturing process and corresponding FDA-approved specifications—a change Genentech cannot make without prior FDA approval. *See Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); 21 U.S.C. § 356a(c); 21 C.F.R. § 601.12(b)(2)(i).

Consequently, the scope of documents relating to these issues is fairly narrow, and many of Plaintiffs' factual allegations have no bearing on whether their claims are preempted. Nonetheless, in accordance with the Court's direction, Genentech broadly construed the preemption issue and produced thousands of pages of responsive documents to Plaintiffs—including the CMC of the BLA. Genentech, consistent with its longstanding position regarding the sensitive nature of these trade secrets, designated these documents as Attorneys' Eyes Only. Genentech was circumspect in its designation, as only the CMC was designated Attorneys' Eyes Only.

Plaintiffs have asserted that there is no risk from unlimited disclosure because Plaintiffs are not competitors of Genentech. At the Case Management Conference, counsel for Genentech explained why that argument is misguided:

> MS. DONAHUE: [I]t's a great, you know, fear for Genentech that even, you know, the two people that may be designated from each of these entities, **even though they're not competitors, per se, and they're not seen as doing business with them, once the information's out there, it's a very slippery slope**. And given the level of highly, highly, highly confidential trade secret information that we're talking about, I cannot overstate the importance of this issue from Genentech's, you know, competitive and trade secret point of view. It's just -- it's so important to them, and I don't think that we're asking for too much; the attorneys' eyes only and the expert person matter because it will be covered under the confidentiality agreement. And if others need to see it, we can address that on a case-by-case basis. But **given the number of plaintiffs we've got and the type of information we're talking about at this point**, we would respectfully request our point of view.

See Exhibit 2 at 40:17-25; 41:1-14 (emphases added). The Court itself recognized the broad scope of the potential disclosure: "Well, if you have two of each client, you're up to about 30?" *Id.* at 38:13-14.

Plaintiffs' assurances that they will protect Genentech's information are insufficient. As numerous courts have recognized, "'[i]t is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the effort may be to do so." *Suture Express, Inc. v. Cardinal Health 200*, LLC, No. 12-2760-RDR, 2013 U.S. Dist. LEXIS 181550, at *28 (D. Kan. Dec. 31, 2013) (quoting *Sullivan Mktg. v. Valassis Commc'ns, Inc.*, No. 93 Civ. 6350 (PKL), 1994 U.S. Dist.

LEXIS 5824, at *9 (S.D.N.Y. May 5, 1994)); *see also e.g.*, *Edisync Sys., LLC v. Adobe Sys.*, No. 12-cv-02231-MSK-MEH, 2013 U.S. Dist. LEXIS 20044, at *4 (same); *Hanford Norbrook Labs. Ltd. v. G.C. Hanford Mfg. Co.*, No. 5:03-CV-165 (HGM/GLS), 2003 U.S. Dist. LEXIS 6851, at *16 (N.D.N.Y. Apr. 24, 2003) (same). Even assuming the Plaintiffs use their best efforts to abide by the protective order, it will be virtually impossible for them to erase the knowledge they learn from the Herceptin® BLA.

In light of the significant risks to Genentech and the utter lack of benefit to Plaintiffs, the calculus is straightforward. Under an Attorneys' Eyes Only designation, Plaintiffs' counsel and retained expert(s)—who, unlike Plaintiffs, presumably have relevant knowledge—would have access to the Herceptin® BLA. Without such a designation, Genentech risks losing a decade of research and development, millions of dollars, and considerable human capital.

CONCLUSION

For the foregoing reasons, Defendant Genentech, Inc. respectfully requests that the Court enter a protective order limiting the disclosure of documents designated by Genentech as "Attorneys' Eyes Only" to Plaintiffs' counsel and retained expert(s).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I herby certify that on the 25th day of July, 2016 the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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